DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

9300721

December 27, 2001

WARNING LETTER
CHI-13-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Nick Suru, President
"N" TECH Instrument Repair, Inc.
25775A Hillview Court
Mundelein, IL 60060

Dear Mr. Suru:

During the inspection of your firm from March 26 to March 28, 2001, Investigator Matthew Sienko determined your firm manufactures lapyroscopes, arthroscopes, and cytoscopes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish a policy and objectives for, and commitment to, quality.

2. Failure to establish procedures for management to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system satisfies the requirements of 21 CFR Part 820 and an establish quality policy and objectives.

3. Failure to establish a quality plan that defines the quality practices, resources, and activities relevant to devices that are designed and manufactured.

4. Failure to establish and maintain procedures to control the design and design changes of devices to ensure that specified design requirements are met.

Your firm's devices are also misbranded within the meaning of Section 502(t)(2) in that your firm failed to establish medical device reporting procedures as per 21 CFR Part 803, Medical Device Reporting (MDR).

Section 502(b) of the Act requires that the device in package form bear a label containing the name and place of business of the manufacturer, packer, or distributor. The inspection revealed that your firm distributes scopes that fail to bear a label that identifies the name and place of business of the manufacturer, or distributor, to [redacted] dealers ([redacted], [redacted], and [redacted], [redacted]). All devices should have proper identification of the manufacturer or distributor.

Section 502(a) of the Act requires that device labeling do not contain statements that are false and misleading. The inspection revealed that the "N" Tech Laparoscopes User's Manual, page 2, indicated the address of your firm as "25097 N. Abbey Glenn Drive, Hawthorn Woods, IL 60047." Also, your firm's phone number is indicated as "847-550-0241." This address and phone number is incorrect. The correct address should be present on all labeling.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine that your systems caused the problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 30 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Michael Lang, Compliance Officer.

If you have any questions regarding this letter, please contact Mr. Lang at (312) 353-5863 x171.

Sincerely,

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Raymond V. Mlecko
District Director